

APPLICATION

of

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for

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on

SINGLE-PIECE THICK-WALLED ENDOPROSTHESIS

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BACKGROUND OF THE INVENTION

This invention relates to medical devices for the treatment of vascular diseases generally referred to as endoluminal prostheses. A variety of such devices are available for a broad range of treatment modalities. Examples of such devices are "vascular grafts" and "stents." Vascular grafts are typically used to treat weakened areas of vessels known as aneurysms. Stents are typically used to prop open a narrowed or stenosed vessel.

Stents and grafts may be delivered intraluminally through a narrow incision or acupuncture in the patient's skin. The device may be mounted on a delivery catheter and inserted into a corporeal lumen through the skin. The device and catheter are then advanced through the various lumens to the site to be treated. To accomplish this, stents and grafts are generally collapsible for delivery and expandable for treatment.

Vascular grafts are primarily composed of an artificial lumen which isolates the natural lumen from the flow of bodily fluids, such as blood. Grafts may incorporate attachment devices to secure the graft into the natural lumen and keep the graft expanded.

Stents are typically formed of metallic wire or bars configured in a cylinder. Prior art stents have generally taught that the resulting thickness of the cylinder should be kept small to provide as large of an open lumen as possible. They have also taught the use of wide bar elements to compress plaque or tissue and hold it against the lumen wall. These stents expand by configuring the elements of the cylindrical structure such that they bend from a generally longitudinal orientation while compressed to a more circumferential orientation while expanded. These bending elements are then connected by elements which typically lie and remain in a circumferential orientation. This configuration limits the compressibility of the prior art stents because elements in a circumferential orientation cannot be tightly packed and thin elements in a longitudinal orientation tend to overlap.

while compressed. Furthermore, this configuration causes stress concentrations by limiting the portions of the structure that bend during expansion and compression.

At least one prior art device has incorporated the benefits of a cylindrical structure composed of flat wires. This device is described in U.S. Patent No. 5,993,482 (Chuter) as 5 a Flat-Wire Stent. The teachings of that patent application are hereby incorporated by reference.

The Chuter flat-wire stent teaches a stent comprised of flat-wires which results in a relatively thick-walled structure. These flat wires are bent into the desired configuration and connected together. This approach has proven to have many advantages. The Chuter 10 flat-wire stent exhibits a greater expansion ratio than other prosthesis. This is due in part to superior packability when compressed. Other advantages include a reduction in stress concentrations while expanded and the minimizing of foreshortening during expansion.

The Chuter flat-wire stent is composed of several springy wires connected together. This requires connection of the wires at multiple locations. The manufacturing 15 process can be highly detailed and time consuming. The finished product comprises multiple elements connected together. The completed Chuter flat-wire stent can benefit from the advantages of the present invention. For example, the connection points of the present invention are less bulky than those of the Chuter flat-wire stent. Furthermore, the present invention reduces stress concentrations in the structure.

20 What has not been taught by the prior art and heretofore unknown is an endoluminal prosthesis which is highly compressible and expansible while eliminating stress concentrations in the structure. The present invention satisfies that need.

SUMMARY OF THE INVENTION

Briefly and in general terms, the present invention relates to an improved endoluminal prosthesis. This prosthesis may function as a stent or as a means to secure an endoluminal graft in a corporeal lumen such as an artery. Stents typically are used to 5 ensure the patency of diseased corporeal lumens by resisting collapse and occlusion.

Endoluminal grafts typically are used to isolate diseased corporeal lumens from the flow of bodily fluids.

The prosthesis incorporating the present invention is configured as a series of intermittently merging curved beams (e.g. leaf springs) formed into a cylinder. This 10 cylindrical structure is capable of being compressed into a small diameter or expanded into a large diameter. To facilitate both compression and expansion the beams have a cross-section which is greater in the radial direction (thickness) than in the circumferential direction (width). The beams of the present invention are also continuously curved to reduce or minimize stress concentrations in the structure. The 15 beams straighten during compression until they are nearly straight.

While compressed the thickness of the beams prevents overlap. In a tightly packed configuration, the curved beams straighten out, come together and generally lie flat in close proximity to each other. The beams resist overlap because the thickness of each beam requires substantial radial displacement to move over or under the adjacent beam.

20 While expanded and during expansion, the thickness of the beams and the configuration of the beams increase the strength of the prosthesis and reduce or minimize stress concentrations. Thicker beams provide for more material in the radial direction to prevent radial collapse. The curved configuration of the beams spreads the bending due to expansion throughout the entire length of the beam. This prevents one area of the

beam from generating most of the bending and withstanding resultant stress concentrations.

The present invention is a single integrated structure without welds or fasteners. This may be accomplished by removing almond-shaped cells from a thick-walled cylinder. This eliminates the need to construct the prosthesis from individual pieces and possible weak points created by fasteners or joining.

In a first embodiment, the prosthesis may have curved beams which are only merged to adjacent beams at their end points. This creates a single repetitive pattern around the circumference of the cylinder, with each beam merged to opposite adjacent beams at opposite end points. This embodiment may be viewed as the simplest structure to include the invention described herein. It includes alternating half-cells divided by curved beams. This embodiment is not necessarily short, as the beams may be of any length. However, it may be viewed as the shortest configuration for any given cell size.

In a second embodiment, the prosthesis may have curved beams like leaf springs which are repeatedly merged to alternating adjacent beams throughout their length. This second embodiment may also be viewed as the single repetitive pattern of the first embodiment repeated throughout the length of the prosthesis. For example, a prosthesis may be comprised of two or more of the single pattern prosthesis connected end to end.

Instead of actually connecting the prosthesis, they may be formed as a single structure.

20 Thereby, the beams could be viewed as continuous throughout the length of the prosthesis. The beams would then have many curved portions which bring them in connecting with alternating adjacent beams at merge sections.

In the compressed condition the prosthesis may be intraluminally inserted and delivered within a corporeal lumen. Once delivered to the site to be treated, the

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prosthesis may be expanded and imbedded into the interior of the lumen. Various methods for intraluminally expanding prostheses are well-known in the art. Expansion due to spring forces is particularly suited for this invention. The highly elastic properties of Nickel-Titanium alloys (for example Nitinol) allow a great amount of expansion and compression of structures without permanent deformation. Thus a prosthesis made of such material may be compressed into a very small configuration, and will spring back into a preset form when released. Other known methods of expansion include balloon expansion, and expansion due to the super-elastic properties of certain alloys. The present invention may also be balloon expandable. To expand the prosthesis by balloon an angioplasty-type dilation catheter is inserted through a compressed or not-fully expanded prosthesis until the balloon portion of the catheter is longitudinally aligned within the prosthesis. The balloon is then expanded forcing the prosthesis radially outwardly.

Once expanded the prosthesis remains in the expanded condition, and the strength of the prosthesis resists radial collapse. When used alone the prosthesis can expand and resist re-collapse of a previously collapsed or stenosed corporeal lumen. When used in combination with a graft, the prosthesis can maintain the graft open and secure the graft to the vessel.

These and other advantages of the invention will become more apparent from the following detailed description of the preferred embodiments. When taken in conjunction with the accompanying exemplary drawings the person of skill in the art will appreciate that various embodiments incorporate the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first embodiment of the prosthesis in an expanded condition.

5 FIG. 2 is a perspective view of the first embodiment of the prosthesis in a compressed condition.

FIG. 3 is a cross-sectional view of the first embodiment of the prosthesis in an expanded condition.

10 FIG. 4 is a cross-sectional view of the first embodiment of the prosthesis in a compressed condition.

FIG. 5 is a perspective view of a second embodiment of the prosthesis.

FIG. 6 is a side view of a third embodiment of the prosthesis.

FIG. 7 is a top view of a portion of a flat pattern for the prosthesis.

FIG. 8 is a side view of a fourth embodiment of the prosthesis.

15 FIG. 9 is a side view of a vascular graft secured in a corporeal lumen by a prosthesis.

FIG. 10 is a side view of a prosthesis embedded in a corporeal lumen.

FIG. 11 is a perspective view of a thick-walled cylindrical tube with cells designed therein.

20 FIG. 12 is a flat pattern view of a portion of a prosthesis embodying variable thickness beams.

FIG. 13 is a flat pattern view of a portion of a prosthesis including alternative embodiments of variable thickness beams.

FIG. 14 is a flat pattern view of a portion of a prosthesis including additional alternative embodiments of variable thickness beams.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following description as well as the Figures describe embodiments of the invention. These embodiments are exemplary of the inventors known uses of the invention, and are not intended to limit the scope of the claimed invention. Those skilled in the art of endoluminal devices will appreciate that the invention described herein may encompass many embodiments.

As shown in the Figures, the present invention relates to an endoluminal prosthesis. More particularly, the invention is an expandable and compressible prosthesis for repairing corporeal lumens. The prosthesis may be formed from a metallic cylinder by removal of cells.

As depicted in Figures 1 and 2, the result of removing cells 20 from the metallic cylinder 22 is a prosthesis 24 comprised of a series of curved beams 26 and merge sections 28. It is to be recognized that the prosthesis 24 shown in FIG. 2 can be compressed, where desired, to a smaller diameter such that the cells 20 are essentially defined by slits (not shown).

The beams 26 are generally longitudinal members circumferentially spaced about the prosthesis 24. In one embodiment, as depicted in FIG. 5, the ends of these beams 26 merge with the ends of circumferentially adjacent beams to form the merge sections 28 only at the ends of the prosthesis. The ends of each beam 26 merge with one adjacent beam on the forward end 30 and the opposite adjacent beam on the rear end 32. This creates a single circumferential pattern of staggered half-cells 21 divided by beams 26. (For comparison, a full cell 25 is identified in FIG. 1). Preferably, the beams 26 each comprise at least two curved segments 34 of opposite orientations and an inflection point 36 near the mid-point of the beams.

In the embodiment depicted in FIG. 5, the merge sections 28 comprise either the forward ends 30 or rear ends 32 of two such beams 26 as well as the ends of the prosthesis. These merge sections 28 are also circumferentially spaced about the prosthesis 24, preferably equidistantly.

5 The single pattern as depicted in FIG. 5 may be extended to build longer prostheses 24. This may be done by extending the length of each beam 26 with additional curved segments 34 and forming additional merge sections 28. This forms the prosthesis 24 as depicted in FIGS. 1 and 2. Alternatively, multiple single patterns may be connected with a separate connector element 58. The connector elements 58 may have various 10 configurations and be distributed throughout the prosthesis 24 in a variety of arrangements. Such a prosthesis 24, having "S"-shaped connector elements at each merge sections depicted in FIG. 6. Other embodiments (not shown) may have connectors with other shapes only at every second or third merge section. Such embodiments may have advantages in providing longitudinal flexibility to the prosthesis 24.

15 In the embodiments depicted in FIGS. 1 and 2 the beams 26 may extend beyond the first merge sections 28 to form additional merge sections 28. This configuration may also be viewed as the merge sections 28 connected end-to-end with opposite facing merge sections 28. This may provide for a prosthesis 24 of greater lengths. The continuous beams 26 of this embodiment merge with adjacent beams 26 repeatedly and 20 alternately throughout their length. The continuous beams are comprised of multiple curved segments 34. The merge sections 28 may also contain flat segments (not shown).

As depicted in FIGS. 3 and 4 the prosthesis 24 is preferably formed from a thick-walled cylinder 22. The difference between the external radius of the cylinder and the internal radius of the cylinder defines a radial thickness 40. Preferably, the cells 20 of the

prosthesis 24 are removed such that the remaining beams 26 have a width (measured circumferentially) 42 that is less than the radial thickness 40. A typical design might have dimensions of .007" circumferential width 42 and .014" radial thickness 40. This defines a deep cross-section for the beams 26. To take advantage of the benefits of this invention,

5 the radial thickness 40 of the beams 26 needs to be substantially greater than the circumferential width 42. Preferably, the radial thickness 40 will be at least one and one-third (1 $\frac{1}{3}$) times the circumferential width 42.

A theoretical flat pattern of the beams 26 and merge sections 28, as depicted in FIG. 7 reveals the novel configuration of the beams. Preferably, each beam 26 is 10 continuously curved, alternating between curves 56 of opposite orientations throughout its length. In this ideal configuration, the beams 26 form inflection points 36 between the opposite facing curves 56.

Each curve 56 in each beam 26 is defined by two radii, an internal radius 64 and an external radius 66. The difference between these radii define the circumferential width 15 42 of the beam 26.

The continuously curved configuration of beams 26 disposed longitudinally along a cylinder, provides some of the unique properties of this invention. As the cylinder is expanded from a partially compressed configuration 50, the radii of each curve 56 within each beam 26 becomes smaller as the beams spread apart. Since the beams 26 are ideally 20 continuously curved, the bending is spread throughout the entire length of the beam 26. This spreads the resultant stresses throughout the beam 26 and reduced or minimizes stress concentrations.

As depicted in FIGS. 2 and 4 the use of deep cross-sections has significant advantages for collapsing the prosthesis 24 in preparation of intraluminal delivery. The

deep cross-section allows for significant compression without incidental overlapping of the beams 26. The large radial thickness 40 of the beams 26 prevents one beam from extending over the top of another.

As depicted in FIGS. 1 and 3 there are also advantages to the use of deep cross-sections in expansion of the prosthesis 24. In general, as cylindrical, expandable prostheses are expanded, longitudinally-oriented members of the collapsed prosthesis tend to bend circumferentially. The relatively narrow width of the beams 26 of the present prosthesis 24 permits circumferential bending without inducing high stress concentrations. The large overall cross-sectional area of the beams 26 prevents 10 compression of the prosthesis 24. The configuration of the curved segments 34 spreads the stresses induced by expansion across the entire length of the beams 26, also reducing stress concentrations. In a preferred embodiment, the prosthesis is self-expandable. Alternatively, the prosthesis may be expanded by balloon.

FIGS. 1 and 3 and FIGS. 2 and 4 depict two separate configurations of the 15 prosthesis 24. The prosthesis 24 of the present invention has an expanded configuration 44 while deployed in the lumen as depicted in FIGS. 1 and 3. This configuration has a large inner diameter which allows maximum patency of the lumen 46 to be treated. The prosthesis 24 of the present invention also has a second partial compressed configuration 50 as depicted in FIGS. 2 and 4. This configuration is beneficial to the intraluminal 20 delivery of the device which is facilitated by a smaller external diameter.

In a typical procedure the prosthesis 24 will be constrained in the compressed configuration 50 within a catheter. This catheter may then be inserted into a small diameter lumen 46 such as the femoral artery. To prevent damage to such an artery the entire system of catheter and prosthesis 24 must have as small a diameter as possible.

Small diameters also facilitate the navigation of the prosthesis 24 and catheter through arduous vasculature. Once inserted into such an artery, the catheter and prosthesis 24 may be advanced through the corporeal lumens, possibly to larger arteries for treatment. The prosthesis 24 may then be released from the catheter. Spring forces within the

5 compressed prosthesis of a self-expanding version will force the prosthesis from the partially compressed configuration 50 into the expanded configuration 44. The spring forces may be great enough to expand the lumen of the diseased vessel as the prosthesis 24 expands. These forces will also be great enough to impinge the beams 26 into the tissues of the vessel. This impinging secures the prosthesis 24 and possibly an associated 10 graft 52 into place.

Another embodiment of the prosthesis 24, depicted in FIG. 8, has a conical rather than cylindrical shape while in the expanded configuration 44. In this embodiment, the prosthesis 24 has a cylindrical shape in the compressed configuration 50. Upon expansion, however, a broader end 60 of the prosthesis 24 expands more than a narrower 15 end 62. This conical embodiment of the prosthesis 24 is useful in similarly shaped lumens and various configurations of grafts. The broader end 60 may include cells 20 that are longer and wider in the expanded configuration 44, than those at the narrower end 62.

The prosthesis 24 of the current invention may be used in a variety of procedures, 20 two of which are depicted in FIGS. 9 and 10. As depicted in FIG. 9 one or more prostheses embodying the present invention may be used in the treatment of aneurysms. An aneurysm is a weakening of the vessel wall of a vein or artery, causing a sack to form in the lumen 46 or possibly rupture. When an aneurysm forms in the abdominal aorta, the condition can be life-threatening. A known treatment for aneurysms is the intraluminal

delivery and implantation of a vascular graft 52. Such a graft 52 bypasses the sack formed by the aneurysm and isolates the weakened tissues from the blood flow. To operate properly, the graft 52 must have leak-proof fixation to the healthy vascular tissue on either side of the aneurysm. The prosthesis 24 described herein may provide that

5 fixation at one or more ends of the graft 52. The prosthesis 24 may also extend throughout the length of the graft 52. When expanded the prosthesis 24 may compress the flexible graft material 52 against the arterial wall. Preferably, the prosthesis 24 extends further from the aneurysm than the graft 52 so that parts of the prosthesis 24 are imbedded in healthy tissue. This configuration maintains the patency of the artificial

10 lumen of the graft 52 as well securing the graft in place by forcing the end of the graft against the wall of the lumen 46. The prosthesis 24 also ensures a leak-proof seal.

As depicted in FIG. 10, a prosthesis 24 embodying the present invention may be used to treat a stenosis or collapse of the lumen 46. Stenosis is often caused by the gradual occlusion of veins or arteries through the build-up of plaque. Preferably a single prosthesis 24 is inserted into the diseased vessel while mounted within a catheter. When the prosthesis 24 is at the location of the narrowing, the prosthesis 24 may be expanded.

15 As depicted in FIG. 10 the spring forces of the prosthesis are preferably sufficient to expand the narrowed vessel. The prosthesis 24 is thereby forced into the tissues of the lumen 46 to secure the prosthesis 24 in place. The structure of the prosthesis 24 resists

20 collapse after expansion.

The prosthesis 24 may be manufactured in the compressed configuration 50 as in FIG. 2, or in the expanded configuration 44 as in FIG. 1 or in any configuration in between. The manufacturing procedure requires the removal of cells 20 from a thick-walled cylinder 22. This may be accomplished with several known manufacturing

methods such as laser cutting, chemical etching, photo-etching, electrical discharge machining (EDM) and mechanical means. Two materials found to be particularly suited to this application are implantable stainless steel, and Nickel-Titanium alloys such as Nitinol.

5 As depicted in FIG. 11, each cell 20 of the endoprosthesis 24 may consist of two sides 54 having three curves 56, and two inflection points 36. Such a configuration produces almond-shaped cells. There may also be flat portions (not shown) designed into the cell 20. These cells 20 are then designed on the thick walled cylinder 22 in a pattern which repeats along the length of the cylinder 22. This pattern is then repeated with a 10 longitudinal stagger of half a cell 20 around the circumference of the cylinder 22. The pattern also includes half cells at each end of the tube. Upon removal of the cells 20 the remaining material constitutes the prosthesis 24 described herein.

The prosthesis 24 may be formed from a thick walled cylinder 22 approximately the size of the compressed configuration 50. This thick walled cylinder 22 may be a 15 Nickel Titanium alloy. Cells 20 are laser cut into the thick walled cylinder 22 while the thick walled cylinder 22 is mounted over a wire. The cells 20 are formed in a long narrow configuration, with each of the curves 56 having large radii.

After the cells 20 are cut into the thick walled cylinder 22, the prosthesis 24 is cleaned and deburred to eliminate manufacturing irregularities. This may include blasting 20 techniques, acid etching, ultrasonic cleaning and/or other well known methods of cleaning.

The prosthesis may then be stretched into more expanded configurations. One method of expanding this prosthesis is by mechanically stretching it over a mandrel. The mandrel may be specifically designed with pins to maintain the desired curvature of the

beams. Once stretched the prosthesis is annealed to set the new expanded shape of the prosthesis. Annealing can be accomplished by heating the prosthesis within a variety of media such as air, molten salt, inert gas or vacuum. Annealing at 500-550°C is appropriate for Nickel-Titanium alloys. After stretching the prosthesis 24 is cleaned 5 again. This process of stretching, annealing and cleaning can be repeated until the desired configuration is obtained. Once the desired configuration has been obtained, the prosthesis is electropolished by any of the well-known methods.

Alternatively, a prosthesis 24 may be formed from a Nickel Titanium thick walled cylinder 22 approximately the size of expanded configuration. In this process cells 20 are 10 cut into the thick walled cylinder in a shorter and wider configuration. This method would eliminate the need to stretch and anneal the prosthesis 24 to achieve the expanded configuration 94.

As best seen in FIGS. 12-14, it is also contemplated that the beams of a prosthesis may embody variable widths beams or struts 60 and generally uniform width beams or 15 struts 61. The incorporation of variable width struts 60 into a prosthesis facilitates uniform expansion. For example, to achieve uniform expansion, it is desirable to have struts 60 of the same width meeting at connecting junctions 62. Asymmetric prosthesis portions 64, 66 as shown in FIGS. 12 and 13 may further require the strut 60 to embody a width that gradually varies along the length of the strut 60. Moreover, as shown in FIG. 20 14, where a prosthesis portion 68 embodies a plurality of adjacent oriented cells 70, the point of connection 72, 73 between adjacent cells 70 may be varied in length, for example to accommodate a hole 74. To facilitate uniform expansion of such a prosthesis portion 68, the struts 60 extending from a relatively shorter point of connection 72 between adjacent cells 70 can embody a tapering thickness.

While the present invention has been described herein in terms of a prosthesis for the repair of blood vessels, those of skill in the art will readily recognize that prostheses embodying the described invention can be used to treat a variety of corporeal lumens, for example the bronchial tree and intestines. The invention described herein is intended to

5 be limited only by the claims that follow and not by any particular embodiment.

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